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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,266	05/13/2005	Ian Revie	1781-0009	5525

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EXAMINER	
CHAWAN, SHEELA C	
ART UNIT	**PAPER NUMBER**
2624	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,266	REVIE ET AL.	
	Examiner	Art Unit	
	SHEELA C. CHAWAN	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/21/10; 4/28/09; 8/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 4/28/09; 8/20/04; 9/21/10, the information disclosure statement is being considered by the examiner.

Drawings

3. The Examiner has approved drawings filed on 8/20/04.

Claim Objections

4. Claims 1, 10 and 11 are objected to because of the following informalities:

In claim 1, line 5, change " ," to -- ; -- .

In claim 1, line 6, change " ," to -- ; -- .

In claim 10, line 5, change " ," to -- ; -- .

In claim 11, line 4, change " ," to -- ; -- .

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al., (US. 6,478,802), in view of Gillies et al., (US.6,272,370).

As to claim 1 , Kienzle, III et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the instrument bearing a plurality of markers rings arranged in a predetermined pattern, which are more reflective than the surface of the instrument (see Figs. 1-2 and Col. 4, Lines 25-43), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the

reel drill bit relative to the receiving device(see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. teach that it is well known within the art of localizing devices to use an optical localizer that employs a stereoscopic camera system to view infrared light emitters or reflectors that are placed on the surgical instruments and that any arrangement of emitters that allows the localizer to determine the pose of the drill emitter coordinate frame with sufficient accuracy may be used without departing from the instant invention. However, Kienzle, III et al. are silent with respect to a plurality of markers rings are arranged in a predetermined pattern on the surface of the shaft. Gillies et al. teach of an analogous endoscopic apparatus comprised of an elongate shaft with a plurality of MR-visible markers 6 disposed at the distal end to provide easily identifiable reference points for trackability and localization under MR imaging and X-ray fluoroscopy (see Figure 1 and col. 25, lines 39-43). The markers 6 can be formed of radio opaque materials, such as gold, platinum or tantalum, which are more reflective than the copolymer of the shaft 2 of the microcatheter 1 (see col. 25, lines 10-53). As seen in figures 2 and 4a-b, Gillies et al. teach of placing the radioopaque materials in rings around the shaft of the instrument and wherein the planes defined by the axially spaced edges of each marker 6 are parallel to one another and perpendicular to the axis of the shaft 2. It would have been obvious to one skilled in the art at the time the invention was made to place a plurality of marker rings around the shaft of the drill bit in the apparatus of Kienzle, III et al. in order to more accurately define the location and orientation of the shaft as it enters the body as taught by Gillies et al.

Regarding claim 2, it is interpreted and thus rejected for the same reasons as applied above in the rejection of claim 1.

As to claim 6, Kienzle, discloses a system as claimed in claim 1, which comprises two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the tool (column 1, lines 15-30).

6. Claims 3 – 5, 7 and 9, are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al., (US.6,272,370), as applied to the above claims and further in view of Ben-Haim (US.6,203,493).

As to claim 3 – 4, Gillies et al. teach two markers 6 on the microcatheter 1 (see Figure 1). However, Ben-Haim discloses a similar tracking device for an endoscope comprised of a sheath 20 having a plurality of sensors 22 spaced along the axis of the endoscope (see Figure 1). Furthermore, duplicating the components of a prior art device is a design consideration within the skill of the art. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the microcatheter 1 with at least three markers 6, in the manner disclosed by Ben-Haim. Furthermore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the microcatheter 1 of Gillies et al. with a sheath containing the markers 6, in the manner disclosed by Ben-Haim, as Ben-Haim demonstrates that sheaths containing radio-opqaue markers for placement over an surgical device are well known in the art.

As to claim 5, Gillies discloses a system as claimed in claim 1, which includes a drive unit for imparting rotational motion to the tool (column 12, lines 1-25).

As to claim 7, Gillies discloses a system as claimed in claim 1, in which the planes defined by the axially spaced edges of each ring are parallel to one another and perpendicular to the axis of the shaft (fig 1, shows that the planes defined by the axially spaced edges of each marker 6 are parallel to one another and perpendicular to the axis of the shaft 2).

As to claim 9, Gillies discloses a system as claimed in claim 1, in which the tool is a cutting tool (fig 1, column 13, lines 37- 41).

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III et al. (U.S. Patent No. 6,478,802) in view of Gillies et al. (U.S. Patent No. 6,272,370) in further view of Ben-Haim (U.S. Patent No. 6,203,493).

Regarding claim 8, Kienzle, III et al. and Gillies et al. disclose a surgical instrument system, which comprises: a drill bit 105 including an elongate shaft which defines a drill bit axis, the shaft bearing a plurality of markers rings arranged in a predetermined pattern (see Figs. 1-2 and Col. 4, Lines 25-30), at least two receiving devices which are spaced apart for receiving stereoscopic signals from the rings on the drill bit (see Col. 1, Lines 15-30), a data processor for analyzing the signal from the rings and generating information relating to the position and orientation of the reel drill bit relative to the receiving device (see Fig. 4), and a drive unit operable to rotate the reel drill bit about the drill bit axis (see Col. 4, Lines 1-10). Kienzle, III et al. are silent with respect wherein the rings

are marked on a sleeve which is fitted onto the instrument. Ben-Haim teaches a similar tracking device for an endoscope comprised of a sheath 20 having a plurality of sensors 22 spaced along the axis ofthe endoscope (see Figure 1). It would have been obvious for one of Ordinary skill in the art at the time the invention was made to provide the instrument of Kienzle, III et al. and Gillies et al. with a sheath containing the markers 6, in the manner disclosed by Ben-Haim, as Ben- Haim demonstrates that sheaths containing radio-opaque markers for placement over an surgical device are well known in the art.

8. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (U.S. Patent No. 6,272,370).

In regard to claims 10 and 11, Gillies et al. teach a microcatheter 1 comprised of an elongate shaft with a plurality of MR-visible markers 6 disposed at the distal end to provide easily identifiable reference points for trackability and localization under MR imaging and X-ray fluoroscopy (see Figure 1 and col. 25, lines 39-43). The markers 6 can be formed of radioopaque materials, such as gold, platinum or tantalum, which are more reflective than the copolymer of the shaft 2 of the microcatheter 1 (see col. 25, lines 10-53). Inherent in the disclosure of the use of an MR or x-ray imaging device is the use of at least two receiving devices spaced apart for receiving stereoscopic signals from the markers 6 and a data processor for analyzing the signal from the markers 6 and generating information relating to the position and orientation of the microcatheter 1. Gillies et al. disclose the movement of the tip can be actuated by a pusher-wire or

guide-wire inserted into the lumen of the implant/catheter and either driven by motor or advanced by hand, as appropriate to the implant's location, direction of movement, and targeted point of delivery. Thus comprising a drive unit for imparting rotational motion to the tool (see Col. 12, Lines 1-25). Furthermore, the tool is inherently a cutting tool as it penetrates tissue to deliver drug substance to a desired target location (see Fig. 1). Also inherent in the disclosure of the use of an MR or x-ray imaging device are the method steps of locating the axis of the shaft 2 of the microcatheter 1 and locating the center line of each marker and as well as identifying 3 generally rectangular areas which represent the markers 6, determining the location of a line on each of the rectangular areas and determining the angle between the lines on adjacent ones of the rectangles (all done within or by the processor that comprises pad of the MR or x-ray imaging device).

Other prior art cited

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patent Number (US. 6,332,891; 6246898; 5797849).

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEELA C. CHAWAN whose telephone number is (571)272-7446. The examiner can normally be reached on 7.30- 5.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela C Chawan/

Primary Examiner, Art Unit 2624